



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0893]

Agency Information Collection Activities; Proposed Collection; Comment Request; Center for Devices and Radiological Health Appeals Processes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the processes available to outside stakeholders to request additional review of decisions or actions by Center for Devices and Radiological Health (CDRH) employees.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2011-D-0893 for "Center for Devices and Radiological Health Appeals Processes." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in

accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Center for Devices and Radiological Health Appeals Processes

OMB Control Number 0910-0738--Extension

The guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes"¹ describes the processes available to outside stakeholders to request additional review of decisions or actions by CDRH employees. FDA is seeking approval for the reporting burden associated with requests for additional review of decisions and actions by CDRH employees as described in the guidance.

Individuals outside of FDA who disagree with a decision or action taken by CDRH and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including requests for supervisory review of an action, petitions, and hearings. Of these, by far the most commonly used is a request for supervisory review under § 10.75 (21 CFR 10.75) ("10.75 appeal"). Section 517A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360g-1), added by section 603 of the Food and Drug Safety and Innovation Act, includes requirements pertaining to the process and timelines for 10.75 appeals of "significant decisions"

¹ <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm284670.pdf>

regarding 510(k) premarket notifications, applications for premarket approvals (PMAs), and applications for investigational device exemptions (IDEs).

A request for review under § 10.75 should be based on the information that was already present in the administrative file at the time of the decision that is being reviewed as provided in § 10.75(d). Section 517A of the FD&C Act refers to significant decisions regarding the information in the administrative file for premarket notification (section 510(k) of the FD&C Act (21 U.S.C. 360(k))), PMA (section 515 (21 U.S.C. 360e)), and IDE (section 520(g) (21 U.S.C. 360j(g))) submissions that is collected under existing regulations that specify the information manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of medical devices. The information collections associated with these regulations are currently approved by the OMB as follows: the collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 (premarket approval) have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910-0078.

While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the decision under review. The guidance describes the collection of information not expressly specified under existing regulations such as the submission of the request for review, minor clarifications as part of the request, and supporting information.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
CDRH Appeals Processes Guidance Document	35	1	35	8	280

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects a decrease of 15 responses and a corresponding overall decrease of 120 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: March 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-04207 Filed: 3/7/2019 8:45 am; Publication Date: 3/8/2019]